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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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01/23/2004

David G. Quinn

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7590 09/03/2008
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EXAMINER

WACHTEL, EMILY L

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

09/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/764,674	Applicant(s) QUINN, DAVID G.	
	Examiner EMILY WACHTEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-14 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-14 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 5-6, 15-22, and 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 9, 2008.

Response to Amendment

2. The amendments to the specification and abstract have been entered and overcome the prior objections. Except for the informality found on Page 1 [0003] the objection of which is repeated below.

Priority

3. This application claims priority to Application No. 60/351,698, filed on January 24, 2002, and adds and claims additional disclosure not presented in the prior application. Specifically, the independent claims of the current application incorporate matter which is not presented in the prior application. Therefore, the filing date of January 24, 2003 is being accorded to the claims.

Specification

4. The disclosure is objected to because of the following informalities:

Page 1 [0003] --length, however. This-- should read --length, however, this--
Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 12 recites the limitation "said tube" in the last two lines. There is insufficient antecedent basis for this limitation in the claim. It is unclear which is the said tube being referred to, the catheter tube containing two lumens, or the single lumen catheter tube, or the catheter tube assembly.

8. Claim 12 recites the limitation "said catheter tubes" in part b. There is insufficient antecedent basis for this limitation in the claim. It is unclear which tubes are being referred to, the tube containing the two lumens, or both the tube containing two lumens and the tube containing a single lumen.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 7-8 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Burney et al. (US 4,986,814).

With regard to claim 7, Burney et al. teach a catheter and stylet assembly, comprising: a) a catheter tube sub-assembly including an enteral feeding catheter tube having a distal end and a proximal end, said tube having a connector on its proximal end (Fig. 1 catheter 22 with connector 34 is capable of being for enteral feeding); and b) a first stylet sub-assembly including

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a primary flexible stylet having distal and proximal ends, said first stylet sub-assembly also including a first stylet fitting in which the proximal end of said primary stylet is seated (Fig. 1 cannula 24 is functionally equivalent to a stylet and is flexible, Col. 2 lines 44-46, having fitting 44); and c) a second stylet sub-assembly including a secondary flexible stylet having distal and proximal ends, said secondary stylet sub-assembly also including a second stylet fitting in which the proximal end of said secondary stylet is seated (Fig. 1 stylet 26 fitting 50, Col. 2 line 47); d) said first stylet fitting being releasably seated in said connector with said primary stylet extending into said tube and said secondary stylet fitting being releasably connected to said first stylet fitting with said secondary stylet extending into said first stylet fitting and said tube (When assembled all three locking members are releasably seated in/connected to each other. The fitting of the cannula (Fig. 1 element 44) is seated in the fitting of the catheter (Fig. 1 element 34). The stylet fitting (Fig. 1 element 50) is connected to the fitting of the cannula (Fig. 1 element 44, Fig. 2, Col. 2 lines 40-43, 49-52)).

With regard to claim 8, in Fig. 1 of Burney et al. element 50 is taken to be the sleeve fitting for the secondary stylet which connects the first stylet fitting to the second stylet fitting.

With regard to claim 30, Burney et al. teach an enteral feeding catheter and stylet assembly for naso-gastric insertion of the catheter into a patient; comprising: a) a catheter tube sub-assembly including an enteral feeding catheter tube having a distal end and a proximal end, said tube having a feeding connector on its proximal end (Fig. 1 catheter 22 with connector 34 is capable of being for enteral feeding as is connector); b) a first stylet sub-assembly including a primary stylet having distal and proximal ends, said first stylet sub-assembly also including a first stylet fitting in which the proximal end of said primary stylet is seated (Fig. 1 cannula 24 is

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functionally equivalent to a stylet, Col. 2 lines 44-46, having fitting 44); and c) a second stylet sub-assembly including a secondary stylet having distal and proximal ends, said secondary stylet sub-assembly also including a second stylet fitting in which the proximal end of said secondary stylet is seated (Fig. 1 stylet 26 fitting 50, Col. 2 line 47); d) said first stylet fitting being seated in said connector with said primary stylet extending into said tube and said secondary stylet fitting being connected to said first stylet fitting with said secondary stylet extending into said tube through said first stylet fitting (When assembled all three locking members are releasably seated in/connected to each other. The fitting of the cannula (Fig. 1 element 44) is seated in the fitting of the catheter (Fig. 1 element 34). The stylet fitting (Fig. 1 element 50) is connected to the fitting of the cannula (Fig. 1 element 44, Fig. 2, Col. 2 lines 40-43, 49-52)).

With regard to claim 31, in Fig. 1 of Burney et al. element 50 is taken to be the sleeve fitting for the secondary stylet which connects the first stylet fitting to the second stylet fitting and through which the second stylet extends.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 9 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) as applied to claims 7 and 31 above, and further in view of Mar (U.S. Patent 4,771,778).

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With regard to claims 9 and 32, Burney et al. teach a catheter and stylet assembly substantially as claimed. Burney et al. does not teach a visible mark on a stylet located 12 inches from its stylet connector. Mar teaches a marker on a core wire, taken to be functionally equivalent to a stylet, disposed in a catheter (Fig. 2 elements 31 and 46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to place a marker on the stylet in Burney et al. because Mar teaches that marks may be placed on the wire disposed in the catheter. It is advantageous because it is a radiopaque marker that can be viewed using fluoroscopy and aids in observing the position the body (Col. 2 lines 59-60, Col. 4 lines 1-2). It would be a matter of obvious design choice for the location of the mark. The mark will be located as desired by the user depending on how they are going to use viewing the mark via fluoroscopy. Ultimately, the mark is still being used to aid the user in knowing the location, within the patient, of the item it is placed on. For this reason, positioning a mark approximately 12" from its stylet connector would have been an obvious expediency in the art.

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) as applied to claim 7 above, and further in view of Abrahamson et al. (U.S. Patent 5,382,238).

With regard to claim 10, Burney et al. teach a catheter and stylet assembly substantially as claimed. Burney et al. does not teach a catheter with two lumens. However, Abrahamson teaches a catheter tube with two lumens (Col. 3 line 12). This allows a stiffener to be inserted in one lumen leaving the other lumen free for fluid delivery. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a double lumen

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catheter in the device of Burney et al. because Abrahamson et al. teaches using a double lumen catheter. This allows a wire stiffener to be inserted and then the catheter can be used in a conventional manner employing two lumens (Col. 4 paragraph 2). The catheter is capable for use in enteral feeding.

14. Claims 11 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) as applied to claims 7 and 31 above, and further in view of further in view of Quinn (U.S. Patent 5,810,787).

With regard to claims 7 and 31, Burney et al. teach a catheter and stylet assembly substantially as claimed. Burney et al. does not teach a size 8 Fr single lumen catheter with a bullet nose bolus on its distal end. However, Quinn teaches a bolus with a bullet tip section located on the distal end of an 8 Fr tube (Fig. 1, Col. 3 lines 57 and 65). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a catheter consisting of an 8 Fr tube with a bullet nose bolus on the distal end in Burney et al. because it is directly taught by Quinn to apply equally well to all types of catheters (Col. 3 lines 18-22). The catheter is capable for use in enteral feeding.

15. Claims 14 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (U.S. Patent 4,986,814) and Quinn (U.S. Patent 5,810,787) as applied to claim 11 above, and further in view of Frassica (U.S. 6,379,334) and Meng et al (U.S. Patent 6,506,181 B2).

With regard to claims 14 and 34, Burney et al. teach a catheter and stylet assembly substantially as claimed. Burney et al. does not teach a catheter coated with a lubricant. Frassica

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teaches a water soluble lubricant being disposed on the distal tip of a catheter (Col. 17 lines 20, 23-24). Meng et al. teaches that a lubricious material may be disposed on the cavity of a catheter (abstract), putting it on the cavity of the catheter means it is disposed inside the catheter. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply a lubricant inside and outside the catheter adjacent to the bolus in the device of Burney et al. in view of Quinn because Frassica teaches lubricating the distal tip of the catheter, also embodying the outside, this is where the bolus in the application is located, and Meng et al. teaches coating the inside surface of a catheter. There is incentive for lubricating the outside distal area of the catheter to make it more easily maneuvered inside the patient and inside the catheter tube so that the instruments moving inside the catheter, the stylets, move easily.

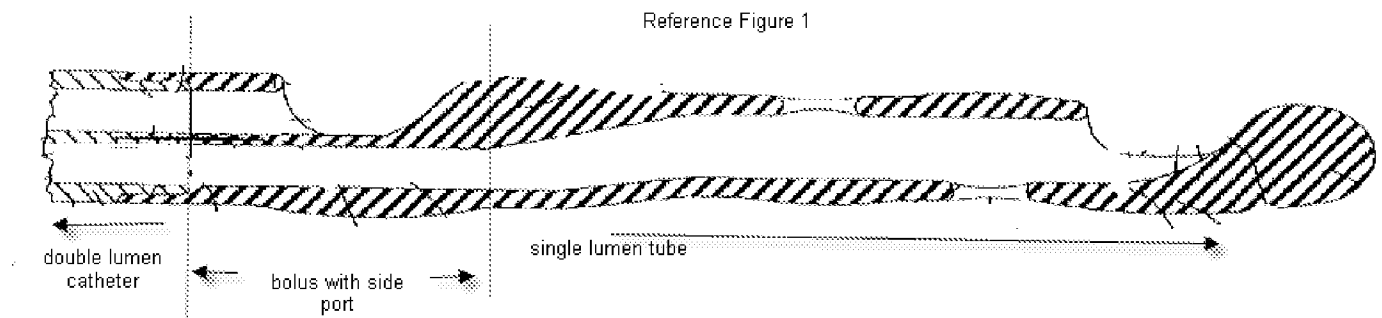
13. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US 2001/0018576 A1) in view of Burney et al. (U.S. Patent 4,986,814).

With regard to claim 12, Quinn et al. teach a catheter and stylet assembly, comprising: a catheter tube assembly including an enteral feeding catheter tube containing two lumens and a smaller diameter enteral feeding catheter tube containing a single lumen; b) said catheter tubes being connected by a bolus having a side port; c) said enteral feeding catheter tube having a proximal and a distal end, said proximal end having a connector on its proximal end (Fig. 27); and d) said smaller diameter enteral feeding catheter tube containing a single lumen (regarding elements a-d see Reference Figure 1 below). The device is capable for use with enteral feeding. Quinn does not teach using an 8 Fr tube. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made use an 8 Fr tube

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because Applicant has not disclosed that such a size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the tube of Quinn because it still allows for adequate fluid delivery. Quinn does not teach first and second stylet subassemblies. However, Burney et al. teach a catheter with a first stylet sub-assembly including a primary stylet having distal and proximal ends, said first stylet sub-assembly also including a first stylet fitting in which the proximal end of said primary stylet is seated (Fig. 1 cannula 24 is functionally equivalent to a stylet, Col. 2 lines 44-46, having fitting 44); a second stylet sub-assembly including a secondary stylet having distal and proximal ends, said secondary stylet sub-assembly also including a second stylet fitting in which the proximal end of said secondary stylet is seated (Fig. 1 stylet 26 fitting 50, Col. 2 line 47); said first stylet fitting being seated in said connector with said primary stylet extending into said tube and said secondary stylet fitting being connected to said first stylet fitting with said secondary stylet extending into said tube through said first stylet fitting (When assembled all three locking members are releasably seated in/connected to each other. The fitting of the cannula (Fig. 1 element 44) is seated in the fitting of the catheter (Fig. 1 element 34). The stylet fitting (Fig. 1 element 50) is connected to the fitting of the cannula (Fig. 1 element 44, Fig. 2, Col. 2 lines 40-43, 49-52)). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a stlyet configuration as taught in Burney et al. in the device of Quinn because it would allow the user to appropriately control and guide the catheter.

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With regard to claim 13, Quinn teaches a catheter and stylet assembly substantially as claimed. Quinn does not specifically disclose the catheter tube being a 5 or 6 Fr size tube. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made use a 5 or 6 Fr tube because Applicant has not disclosed that such a size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the tube of Quinn because it still allows for adequate fluid delivery.

Response to Arguments

14. Applicant's arguments with respect to claims 7-14 and 30-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Wachtel/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767